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10/788,747	02/26/2004	Kenneth W. Carpenter	MEDIV2020-2	8116
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EXAMINER				
HELM, CARALYNNE E				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/788,747

Applicant(s)

CARPENTER ET AL.

Examiner

CARALYNNE HELM

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9, 11, 16 and 18-67 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 16, 20-33, 35-37 and 39-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11, 18, 19, 34, and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

To summarize the current election, applicants elected of Group I and the species where aminoxyls are the bioactive agent and a polypeptide of 2 to about 25 amino acids is the linker. Claim 38 is more properly classified as a linking claim that links groups I, III, and VIII.

Claim 38 link(s) inventions I, III, and VIII. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 38. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall be** withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 7-9, 16, 20-33, 35-37, and 39-67 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on July 8, 2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

If the base claim has been canceled, a claim which is directly or indirectly dependent thereon should be rejected as incomplete (see MPEP 608.01(n) (V)). In this

instance claim 34 depends from claim 17, which has been canceled. Therefore claim 34 is incomplete and the scope embraced by the claim(s) cannot be discerned by one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

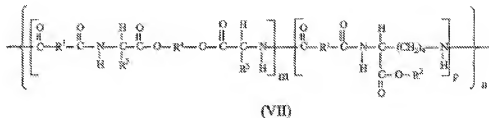
The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 11, 18-19, 34, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (previously cited) in view of Lang et al. (previously cited).

Chu et al. teach a drug (bioactive agent) containing biodegradable polymer coating (see page 2 lines 21-26 and 12 lines 3-13; instant claim 1). These drugs are taught to be covalently connected to the polymer via a linker such that upon degradation, the active drug is released (*in situ* therapeutic effect) (see page 42 lines 1-3; instant claims 1-2 and 38). Chu et al. teach the application of their polymers to the surface of a medical device, where a vascular stent is particularly envisioned (see page 43 lines 1-3 and 9-12; instant claims 1 and 34). A particular set of polymers depicted by formula VII are shown below:



wherein

m is about 0.1 to about 0.9;

p is about 0.9 to about 0.1;

n is about 50 to about 150;

each R¹ is independently (C₂-C₂₀)alkylene;

each R² is independently hydrogen, or (C₆-C₁₈)aryl(C₁-C₆)alkyl;

each R³ is independently hydrogen, (C₁-C₆)alkyl, (C₂-C₂)alkenyl, (C₂-

C₆)alkynyl, or (C₆-C₁₈)aryl(C₁-C₆)alkyl; and

each R⁴ is independently (C₂-C₂₀)alkylene.

(see instant claim 1). This polymer is the same as that instantly claimed as

Formula/Structure VI. Chu et al. go on to teach drugs attached to the polymer chain via a linker. The linker is taught to separate the drug from the polymer by 5 angstroms to 200 angstroms and can be composed of 2 to about 25 amino acids (see page 39 lines 4-7 and 11-13; instant claims 1 and 19). Such a polypeptide chain is envisioned as poly-L-lysine, poly-L- glutamic acid, poly-L-aspartic acid, poly-L-histidine, poly-L-ornithine, poly-L-threonine, poly-L-tyrosine, poly-L-leucine, poly-L-lysine-L-phenylalanine, poly-L-arginine, or poly-L- lysine-L-tyrosine (see page 40 lines 16-22; instant claim 18). A variety of drugs are taught where the aminoxyl, 4-amino-2, 2, 6, 6,-tetramethylpiperidinyloxy (called 4-amino TEMPO), is exemplified (see example 25; instant claims 3-5 and 11). Chu et al. do not provide a complete example with a polymer

of their invention with 4-amino TEMPO attached via a polypeptide linker on an intravascular stent.

Lang et al. teach stents that contain polymers that have an aminoxyl compound covalently linked (see abstract and claim 11). Specifically Lang et al. teach a polymer with the aminoxyl, 4-amino-2, 2, 6, 6,-tetramethylpiperidinyloxy, which they call Tempamine, as a coating on a stent because the aminoxyl compound acts as an anti-inflammatory (see column 6 lines 47-51 and example III).

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the polymer of Chu et al. with a drug attached via a 2 to 25 amino polypeptide linker where the drug is 4-amino TEMPO to an intravascular stent because the drug was 1) an envisioned variety of drug in the invention, 2) falls within the class of envisioned anti-inflammatory drugs, and 3) known to be effective *in situ* as an anti-inflammatory compound when bound to a polymer in a stent coating (see Chu et al. claim 105 and, Lang et al. example III; instant claim 1). Additionally, inflammation is known to be a stage of wound healing whose speedy cessation is desirable. Thus the 4-amino-TEMPO containing polymer promotes endogenous wound healing (see instant claim 3). 4-amino-TEMPO is also known to retard the proliferation of smooth muscle cells due to the action of nitric oxide that it transports in the form of nitroxyl radicals (see instant claims 4-5). Therefore claims 1-5, 11, 18-19, 34 and 38 are obvious over Chu et al. in view of Lang et al.

Response to Arguments

Applicants' arguments filed July 8, 2010 have been fully considered but they are not persuasive.

In light of the amendment to the claim 1 and the cancellation of claims 12-14, the objections to these claims are hereby withdrawn.

Applicants argue that the instantly claimed polymer improves surface hydrophobicity, accessibility toward enzyme activation, and the release profile of the bioactive agent from the polymer while the polymer of Chu et al. in view of Lang et al. is not taught to have these properties. None of these are claimed properties. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, the polymer and linker claimed are the same as that taught by Chu et al. Therefore any property recognized by applicants would also be present in their polymer since a compound and its properties are inseparable. Moreover applicants do not provide a basis for comparison or any evidence to support their assertion of improved properties in the claimed polymer.

In addition, Chu et al. exemplify 4-amino TEMPO as an envisioned drug that is attached to the polymers of their invention; thus there is a suggestion to select this drug to attach to the polymer. Based on the teachings of Lang et al. to attach 4-amino TEMPO (for its anti-inflammatory properties) to a polymer that is then coated on a stent, there was also a motivation for the artisan of ordinary skill in the art to select this same

bioactive for the polymers of Chu et al. that are also taught as coatings on stents. These combined teachings provide a reasonable expectation of success for the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634